Attachment 5

National Association of Boards of Pharmacy

TO: EXECUTIVE OFFICERS – STATE BOARDS OF PHARMACY

FROM: Eleni Z. Anagnostiadis, Professional Affairs Director

DATE: July 1, 2005

RE: FDA Requests Public Comment on Draft Guidance on Useful Written Consumer Medication Information

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The Food and Drug Administration (FDA) has announced the availability of a draft guidance entitled "Useful Written Consumer Medication Information (CMI)." CMI is written information developed for consumers about prescription drugs that is distributed to consumers upon dispensing. The draft guidance discusses general issues and makes recommendations on the content of useful written CMI.

In 1998, NABP was contracted by FDA to conduct a pilot study to evaluate a methodology for assessing the usefulness of CMI in relation to the requirements of existing federal laws. In 2001, NABP conducted a national study to assess the extent to which the year 2000 goals had been achieved pursuant to Public Law 104-180. The results of the study revealed that on average, 89 percent of patients in the study received some form of written medication information; however, the average *usefulness* of the information was only about 50 percent. Subsequently, NABP assisted FDA in 2001 by subcontracting an expert panel which developed criteria in determining if CMI is *useful*.

The Federal Register notice may be obtained from: http://a257.g.akamaitech.net/7/257/2422/01jan20051800/edocket.access.gpo.gov/2005/pdf/05-10445.pdf. The draft guidance document may be obtained from: http:/www.fda.gov/cder/guidance/index.htm.

Comments must be submitted by July 25, 2005 and should be submitted to the Division of Dockets Management (HFA-305), FDA, 5600 Fisher Lane, Rm 1061, Rockville, MD 20857. Alternatively, comments may be electronic submitted to http://www.fda.gov/docets/ecomments.

If you have any questions, please contact me via e-mail at eanagnostiadis@nabp.net or by calling 847/391-4400.

cc: NABP Executive Committee
Carmen A. Catizone, Executive Director/Secretary

National Association of Boards of Pharmacy

1600 Feehanville Drive • Mount Prospect, IL 60056-6014
Tel: 847/391-4406 • Fax: 847/391-4502
Web Site: www.nabp.net

July 20, 2005

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Ln, Room 1061
Rockville, MD 20852

Re: Useful Written Consumer Medication Information: Requests for Public Comment [Docket No. 2005D-0169]

The purpose of this correspondence is to provide comments and suggestions concerning the "Useful Written Consumer Medication Information (CMI)" draft guidance pursuant to the May 26, 2005 Federal Register notice by the United States Food and Drug Administration (FDA). The National Association of Boards of Pharmacy® (NABP®), founded in 1904, represents all of the pharmacy regulatory and licensing jurisdictions in the US, Guam, Puerto Rico, the Virgin Islands, eight provinces of Canada, two states in Australia, New Zealand, and South Africa. NABP's purpose is to serve as the independent, international, and impartial association that assists its member boards and jurisdictions in developing, implementing, and enforcing uniform standards for the purpose of protecting the public health.

NABP has been actively involved in the development of CMI since 1996 when it was appointed a member of the Steering Committee for the Collaborative Development of a Long-Range Action Plan for the Provision of Useful Prescription Medicine Information, which developed the report entitled "Action Plan for the Provision of Useful Prescription Medicine Information." As the FDA draft guidance states, NABP also developed both a pilot study and a national study (Svarstad, BL and JK Mount, *Evaluation of Written Prescription Information Provided in Community Pharmacies*, December 2001) to assess the extent to which the year 2000 goals specified in the law (ie, 75% of people receiving new prescriptions would receive useful written patient information along with them) had been achieved. NABP's active involvement in the development of CMI, that meets the requirement of "useful to consumers," continued with its participation in the National Council on Patient Information and Education's (NCPIE) stakeholder's project, which is still underway.

In 2004, the NABP membership passed Resolution 100-6-04, Medication Identification:

> Whereas, the ultimate goal of all pharmacy practice is to assure positive patient outcomes through the optimization of the correct and most appropriate medication therapy; and

> Whereas, the technology presently exists and is being used in several states whereby a pictorial representation or written description of a drug can be placed on the prescription label and/or printed patient information; and

> Whereas, other states have mandated that a pictorial representation or written description of a drug be placed on most prescription labels; and

> Whereas, the use of a pictorial representation or written description of a drug on a prescription label and/or printed patient information will enhance the opportunity for pharmacists and patients to identify and prevent medication errors before the errors cause harm;

> THEREFORE BE IT RESOLVED that NABP work with interested stakeholders, including manufacturers who develop the digital images and/or written descriptions, to develop, promote, and encourage that all prescription labels contain a pictorial representation and/or written description of the medication.

As result of Resolution 100-6-04 (Medication Identification), NABP has sought assistance from organizations like the American Society of Automation in Pharmacy to identify companies that offer digital imaging and associated technologies. NABP has also urged the Pharmaceutical Research and Manufacturers of America to encourage manufacturers to provide digital images and/or written descriptions to digital imaging companies in order to ultimately promote and encourage the widespread use of pictorial and written descriptions of the medication on prescription labels and printed information (or CMI). Some states, such as California, Georgia, Oregon, and Wyoming currently mandate that the prescription label of dispensed medication contain a written description of the product.

Therefore, NABP encourages the inclusion of pictorials and/or written descriptions (physical description of the medication, including its color, shape, and any identification code that appears on the tablet or capsule) of medications as a specific recommendation of Criterion 1 (Drug Name, Indications for Use, and How to Monitor for Improvement) in the final "Guidance on Useful Written Consumer Medication Information." NABP believes that the inclusion of such information would not only aid in reducing medication errors, but may also assist the patient in identifying products that could be potentially counterfeit or substandard.

If I can provide any additional information, please contact me. Thank you for the opportunity to address this important issue.

Sincerely,

Eleni Z. Anagnostiadis, RPh
Professional Affairs Director

EZA/cj

cc: NABP Executive Committee
        Carmen A. Catizone, Executive Director/Secretary

the role of amplification; models of early intervention; and the need for future research.

Agenda items are subject to change as priorities dictate.

FOR FURTHER INFORMATION CONTACT: Marcus Gaffney, M.P.H., National Center on Birth Defects and Developmental Disabilities, CDC, 1600 Clifton Road, NE., M/S E–88, Atlanta, Georgia 30333. Telephone: (404) 498–3031.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: May 20, 2005.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 05–10541 Filed 5–25–05; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

National Institute for Occupational Safety and Health, Safety and Occupational Health Study Section

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following committee meeting.

Name: Safety and Occupational Health Study Section (SOHSS), National Institute for Occupational Safety and Health (NIOSH).

Times and Dates: 8 a.m.–5 p.m., June 21, 2005. 8 a.m.–5 p.m., June 22, 2005.

Place: Embassy Suites Hotel, 1900 Diagonal Road, Alexandria, Virginia, 22314, telephone 703/684–5900, fax 703/684–1403.

Status: Open 8 a.m.–8:15 a.m., June 21, 2005. Closed 8:15 a.m.–5 p.m., June 21, 2005. Closed 8 a.m.–5 p.m., June 22, 2005.

Purpose: The Safety and Occupational Health Study Section will review, discuss, and evaluate grant application(s) received in response to the Institute's standard grants review and funding cycles pertaining to research issues in occupational safety and health, and allied areas.

It is the intent of NIOSH to support broad-based research endeavors in keeping with the Institute's program goals. This will lead to improved understanding and appreciation for the magnitude of the aggregate health burden associated with occupational injuries and illnesses, as well as to support more focused research projects, which will lead to

improvements in the delivery of occupational safety and health services, and the prevention of work-related injury and illness. It is anticipated that research funded will promote these program goals.

Matters to be Discussed: The meeting will convene in open session from 8–8:15 a.m. on June 21, 2005, to address matters related to the conduct of Study Section business. The remainder of the meeting will proceed in closed session. The purpose of the closed sessions is for the study section to consider safety and occupational health-related grant applications. These portions of the meeting will be closed to the public in accordance with provisions set forth in Section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, Centers for Disease Control and Prevention, pursuant to Section 10(d) Pub. L. 92–463.

Agenda items are subject to change as priorities dictate.

For Further Information Contact: Price Connor, Ph.D., NIOSH Health Scientist, 1600 Clifton Road, NE., Mailstop E–74, Atlanta, Georgia 30333, telephone 404/498–2511, fax 404/498–2569.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: May 20, 2005.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 05–10542 Filed 5–25–05; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0169]

Draft Guidance on Useful Written Consumer Medication Information

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled "Useful Written Consumer Medication Information (CMI)." CMI is written information developed for consumers about prescription drugs that is distributed to consumers when they have prescriptions filled. The guidance discusses general issues and makes recommendations on the content of useful written CMI.

DATES: Submit written or electronic comments on the draft guidance by July 25, 2005. General comments on agency

guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http:// www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Ellen Tabak, Center for Drug Evaluation and Research (HFD–410), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7843.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance entitled "Useful Written Consumer Medication Information (CMI)." This draft guidance is intended to assist individuals or organizations (e.g., pharmacies, private vendors, healthcare associations) in developing useful written CMI. CMI is written information about prescription drugs developed by organizations or individuals, other than a drug's manufacturer, that is intended for distribution to consumers at the time of dispensing. Since neither FDA nor the drug's manufacturer reviews or approves CMI, FDA recommends that the developers of written medication information use the factors discussed in this guidance to ensure that their CMI is useful to consumers.

Traditionally, FDA has believed that when people are well-informed about the medications they take, they are able to make better decisions about their healthcare and better use of the prescription medications available to them. Access to useful written information about prescription medications is important to ensuring appropriate use of these products. In 1996, a steering committee comprised of interested stakeholders (including healthcare professionals, consumer organizations, voluntary health agencies, pharmaceutical manufacturers, prescription drug wholesalers, drug information database companies, CMI developers, and

others), facilitated by the Keystone Center, collaboratively developed a report entitled "Action Plan for the Provision of Useful Prescription Medicine Information" (the Action Plan).[1] The Action Plan outlined criteria for evaluating whether a particular piece of written medical information is useful to consumers. It represented the culmination of a long history of efforts aimed at ensuring that consumers receive useful information regarding their prescription medications.

A. Regulatory History Preceding the Action Plan

Since 1968, FDA regulations have required that patient package inserts, written specifically for patients, be distributed to patients when certain prescription drugs, or classes of prescription drugs, are dispensed (see 21 CFR 310.501 for oral contraceptives and 310.515 for estrogens). FDA regulations also require pharmaceutical manufacturers to develop and distribute written patient labeling called Medication Guides for prescription drug products that pose a serious and significant public health concern (21 CFR 208.1(c)). These Medication Guides are required to be written in nontechnical language (21 CFR 208.20(a)(1)). In addition, drug manufacturers have voluntarily agreed with FDA to produce and distribute patient labeling for many other prescription drugs and classes. A description of how the FDA regulations evolved is provided in the following paragaraphs.

1. The First Proposed Rule That Required Written Patient Information

In the 1970s, FDA began evaluating the general usefulness of patient labeling for prescription drugs and, in 1979, published a proposed rule to require written patient information for all prescription drugs (44 FR 40016, July 6, 1979). In 1980, FDA published a final rule establishing requirements and procedures for the preparation and distribution of manufacturer-prepared and FDA-approved patient labeling for a limited number of prescription drugs (45 FR 60754, September 12, 1980). In 1982, FDA revoked those regulations, in part based on assurances by pharmaceutical manufacturers, healthcare professional associations,

and private-sector providers of written medication information for patients that the goals of the final rule would be met more effectively and with greater innovation without regulation (47 FR 39147, September 7, 1982). FDA committed itself to monitor the progress of this private-sector effort.

2. The Medication Guide Rule

Periodic FDA surveys showed that although the distribution of written prescription drug information increased, the usefulness of the information was highly variable. Consequently, in 1995, FDA published a proposed rule entitled "Prescription Drug Product Labeling; Medication Guide Requirements" (60 FR 44182, August 24, 1995). The proposal was designed to aid patients in receiving useful written information about the prescriptions they were given by setting specific distribution and quality goals and time frames for achieving them. The goals that FDA proposed in the rule were that, by the year 2000, 75 percent of people receiving new prescriptions would receive useful written patient information with their prescriptions; by 2006, 95 percent of people receiving new prescriptions would receive useful written patient information with their prescriptions. The proposed rule also described criteria for usefulness to permit evaluation of whether the information met the target goals.[2] In addition to setting these goals, the proposed rule was designed to require manufacturers to prepare and distribute Medication Guides for a limited number of prescription drug products that posed a serious and significant public health concern.

3. Medication Guide Legislation

On August 6, 1996, as FDA was reviewing the public comments on the 1995 proposed rule, Public Law 104–180 was enacted.[3] It adopted goals and time frames consistent with the 1995 proposed rule. The legislation also required the Secretary of HHS (the Secretary) to request that a representative group of interested stakeholders collaborate to develop a long-range comprehensive action plan (the Action Plan) to achieve the goals specified in the statute. Required

elements of the Action Plan included the following items:
• An assessment of the effectiveness of the current private-sector approaches to providing CMI;
• Development of guidelines for providing effective CMI consistent with the findings of such assessment;
• Identification of components necessary to ensure the transmittal of useful information to the public expected to use the product, including the criteria identified in the 1995 proposed rule; and
• Development of a mechanism to periodically assess the quality of prescription information and the frequency with which that information is provided to consumers.

The law prohibited FDA from taking further regulatory steps specifying a uniform content or format for written information voluntarily provided to consumers about prescription drugs if private-sector initiatives met the goals of the plan within the specified time frames. However, if evaluations showed that the goals were not met, the limitation would not apply, and the Secretary would be required to seek public comment on other initiatives that could meet the goals.

B. The Development and Implementation of the Action Plan

As mentioned previously in this document, a steering committee comprised of interested stakeholders, facilitated by the Keystone Center, collaboratively developed the Action Plan, which the Secretary accepted in January 1997. The Action Plan endorsed the criteria specified in Public Law 104–180 for defining the usefulness of medication information. Specifically, the Action Plan stated that "[p]rescription medicine information shall be useful to consumers" and provided criteria that are intended to define useful CMI. As stated in the Action Plan, useful written information is that which "* * * is sufficiently comprehensive and communicated [in] such [a way] that consumers can make informed decisions about how to receive the most benefit from medicines and protect themselves from harm. Both the substance and presentation of the information are important." Specifically, the Action Plan stated that such materials should meet the following criteria:
• Scientifically accurate;
• Unbiased in content and tone;
• Sufficiently specific and comprehensive;
• Presented in an understandable and legible format that is readily comprehensible to consumers;

- Timely and up-to-date; and
- Useful, that is, enables the consumer to use the medicine properly and appropriately, receive the maximum benefit, and avoid harm.

The Action Plan includes descriptions of the criteria.

1. The Pilot Study That Applied the Action Plan Usefulness Criteria

To test a methodology for assessing the usefulness of CMI in relation to the requirements of the law, FDA contracted with the National Association of Boards of Pharmacy (NABP) to conduct a pilot study. In 1998, NABP arranged for the collection of written materials given to patients who filled new prescriptions for three commonly prescribed drugs from a sample of State pharmacies. An expert panel developed assessment tools, applying the Action Plan criteria, and used them to evaluate the usefulness of the collected CMI materials. The pilot study report[4] was presented by the director of the expert panel and discussed by stakeholders at an FDA public workshop from February 29 to March 1, 2000 (65 FR 7022, February 11, 2000).

2. The National Study That Applied the Action Plan Usefulness Criteria

In 2001, FDA commissioned NABP to conduct a national study to assess the extent to which the year 2000 goals specified in the law had been achieved. A random sample of pharmacies across the continental United States was selected. Patients submitted prescriptions at each pharmacy for four commonly prescribed drugs and collected any written materials given to them when the medications were dispensed. The materials were sent to an expert panel for evaluation against the criteria endorsed by the Action Plan. The results of the study were announced in 2002.

On average, 89 percent of the patients received some form of written medication information. However, the average usefulness of the information was only about 50 percent. The evaluation report[5] is available on the Internet at *http://www.fda.gov/cder/reports/prescriptioninfo/default.htm.*

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[4] Svarstad, B. L. and D. C. Bultman, "Evaluation of Written Prescription Information Provided in Community Pharmacies: An 8-State Study," interim report to HHS and FDA, December 1999, available on the Internet at *http://www.fda.gov/cder/calendar/meeting/rx2000/report1.htm.*

[5] Svarstad, B. L. and J. K. Mount, "Evaluation of Written Prescription Information Provided in Community Pharmacies, 2001," final report to HHS and FDA, December 2001.

3. The Advisory Committee Meeting That Led to the Development of This Guidance

The report findings were presented at an FDA Drug Safety and Risk Management Advisory Committee (Advisory Committee) meeting on July 17, 2002 (67 FR 45982, July 11, 2002). In addition, public comments were requested about the steps the private sector was taking to meet the target goals of Public Law 104–180, possible barriers to meeting the goals and plans to overcome those barriers, the role FDA should take in assuring full implementation of the Action Plan, and other initiatives FDA should consider in facilitating achievement of the goals (68 FR 33724, June 5, 2003). The Advisory Committee recommended that FDA take a more active role in advising and encouraging the private sector to meet the next target goal set for 2006. A transcript of FDA's Drug Safety and Risk Management Advisory Committee meeting on July 17, 2002, is available on the Internet at *http://www.fda.gov/ohrms/dockets/ac/02/transcripts/3874t1.htm.* Subsequent to the Advisory Committee meeting, FDA stated its belief that the voluntary approach to improving the distribution of useful CMI could still work to meet the legislatively mandated 2006 level if efforts to improve began immediately. FDA considered the Advisory Committee recommendations, the public comments, and the findings of strong CMI distribution rates but clear deficiencies in quality, and identified three specific areas in need of consensus and action by the relevant stakeholders to meet the 2006 goal. The following areas were identified: (1) Implementation (identifying roles and responsibilities among the stakeholders and methods for overcoming barriers to meeting the goals); (2) evaluation (determining how quality improvements can be made in areas of CMI deficiencies); and (3) education (implementing procedures so that all CMI developers, pharmacists, and professional associations are aware of the statutory requirements).

The agency met with various groups and held a public meeting in 2003 (see *http://www.fda.gov/cder/offices/ods/writtenprescripinfo.htm*). In these meetings, the agency was asked to provide clarification on how the Action Plan should be interpreted and implemented. This guidance is a result of that request. Specifically, this guidance is intended to provide recommendations to developers of CMI regarding how best to evaluate current CMI and develop future CMI to ensure

that all CMI meet the usefulness criteria provided in the Action Plan. FDA welcomes comments on all the topics addressed by the guidance.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on useful written CMI. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. Submit a single copy of electronic comments or two paper copies of mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm.*

Dated: May 18, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–10445 Filed 5–25–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning

Attachment 6

THE EXPANDED SYRINGE ACCESS DEMONSTRATION PROGRAM (ESAP)

Pharmacy Practices and Experiences Questionnaire

NEW YORK STATE DEPARTMENT OF HEALTH

April 2004

Section A: Personal Background

This section asks for information about you. All responses will be kept confidential.

A1. How long have you been a licensed pharmacist? _____ Years _____ Months

A2. Do you manage the pharmacy that you are currently working in?
    ❑1 Yes   ❑2 No

    A2a. If no, what is your title/role? _____

A3. How long have you worked in this pharmacy?
    ___ Years   ___ Months

A4. Are you involved with setting policy at this pharmacy?
    ❑1 Yes   ❑2 No

Section B: Pharmacy Information

This section asks general questions about your pharmacy.

B1. How many licensed pharmacists are employed at your pharmacy? *(Include full and part-time pharmacists)* Specify number: _____

B2. How many Full Time Equivalent (FTE) licensed pharmacists are employed at your pharmacy? Specify number: _____

B3. Complete the chart below to indicate how many hours per day your pharmacy's prescription counter is open.

If open 24 hours per day, 7 days per week, check here and go to Question B4: ❑

<u>Number of hours open in a typical week</u>

Day	
Monday	_____
Tuesday	_____
Wednesday	_____
Thursday	_____
Friday	_____
Saturday	_____
Sunday	_____

B4. Which category best describes your pharmacy's location? *(Check all that apply)*

    ❑1 Part of a grocery store or other larger retail store
    ❑2 In a mall or shopping plaza without direct street access to your pharmacy
    ❑3 In a mall or shopping plaza with direct street access to your pharmacy
    ❑4 Free standing with direct street access
    ❑5 In a hospital or clinic
    ❑6 Other:_____

B5. Please estimate the percent of your customer base each of the following groups comprise. *(Percentages should add to 100%)*

_____ % Black or African American
_____ % White
_____ % Hispanic or Latino
_____ % Asian or Pacific Islander
_____ % Native American or Alaska Native
_____ % Other (please specify: _____)
_____ % Unknown
Total: 100 %

B6. Estimate the percentage of *prescriptions* for needles/syringes that are filled at your pharmacy that are paid for by the following sources? *(Percentages should add to 100%)*

_____ % Medicaid
_____ % Medicare
_____ % Private insurance carriers
_____ % Self pay/no insurance coverage
_____ % Other, Specify source:_____
Total: 100 %

B7. In your opinion, how many of your customers who buy needles/syringes without a prescription use them to inject illicit substances (e.g., heroin, non-prescription steroids)?

❏99 Not applicable, I haven't sold any.

❏1 All of them
❏2 More than half
❏3 About half
❏4 Less than half
❏5 None of them
❏6 I don't know

B8. Please estimate your perception of the level of illegal drug activity in the neighborhood where your pharmacy is located:

❏1 None
❏2 Very low
❏3 Low
❏4 Moderate
❏5 High
❏6 Very High

Section C: Policies and Procedures

The Expanded Syringe Access Demonstration Program (ESAP) began in January of 2001 and was extended through September, 2007. The following questions address any policies and procedures placed on the over the counter sale of needles and syringes without a prescription by your pharmacy.

C1. What circumstances **reduce** the likelihood that pharmacists in your store sell needles/syringes without a prescription to any given person? (*Check all that apply*)

☐99 Not applicable, pharmacists sell non-prescription syringes in all cases.

☐1 Lack of familiarity with customer

☐2 Customer is known injection drug user

☐3 Customer has disheveled appearance

☐4 Customer appears not to be sober

☐5 Presence of other customers

☐6 Excessive purchases/transactions (Describe)_____

☐7 Safety of self and staff

☐8 Risk of discarded syringes by customer

☐9 Time of day

☐10 Absence of in-store security staff

☐11 Risk of theft or robbery

☐12 Other:_____

Provide additional detail as needed to clarify the responses to C1 above:

_____

_____

C2. Please indicate whether or not your pharmacy has placed any of the following procedures on the sale of needles/syringes without a prescription. *(Check all that apply)*

☐1 Verify customer's age

☐2 Require proof or knowledge of customer's medical condition requiring syringe use (e.g., diabetes)

☐3 Show picture identification for reasons other than age verification

☐4 Name and/or address must be given

☐5 Ask customer to explain why they need the syringes

☐6 Show non-picture identification

☐7 Enter customer name in a log book

☐8 Other: _____

☐9 My pharmacy requires no procedures for selling needles/syringes

C3. Since your enrollment in ESAP, how many times has your pharmacy refused to sell needles/syringes without a prescription to any customers? *(Check one)*

☐1 Never *(Go to C4)*

☐2 Once or Twice

☐3 Between 3 and 10 times

☐4 More than 10 times

C3A. Did you ever refuse to sell needles/syringes because you suspected/knew the person was going to sell them or use them to inject illicit substances?

☐₁ Yes　　☐₂ No

C4. Using the scale below, please indicate whether you include the following in non-prescription syringe transactions:

A. ESAP Safety Insert　　☐₁ Never　☐₂ Sometimes　☐₃ Always
B. Household Sharps Brochure　☐₁ Never　☐₂ Sometimes　☐₃ Always
C. ESAP Diabetes Brochure　☐₁ Never　☐₂ Sometimes　☐₃ Always
D. Other: _____　☐₁ Never　☐₂ Sometimes　☐₃ Always

C5. How do you make the availability of ESAP known to your customers? *(Please check all that apply)*

☐₁ We advertise the program (Describe: _____)
☐₂ We display the ESAP decal
☐₃ Word of mouth
☐₄ Participate in local activities to inform the community of ESAP-registered pharmacies (Describe: _____)
☐₅ We do nothing to make the availability of ESAP known to our customers
☐₆ Other: _____

C6. Has your pharmacy experienced any problems or delays in obtaining the ESAP safety insert?　☐₁ No　☐₂ Yes, Please explain:_____

_____

Section D: ESAP-Related Experiences

This section asks questions about your pharmacy's experiences with ESAP

D1. How are nonprescription needles/syringes sold in your pharmacy? (*Check all that apply*)

☐₁ Individually　☐₂ In packages of 10　☐₃ Other, Specify: _____

D2. How many total needles/syringes did your pharmacy sell without a prescription **during the month of January, 2004**? *Note: Provide the total number of needles/syringes, not the number of transactions.*

☐₁ None　　　　　　　☐₂ 10 or less
☐₃ 11 – 100　　　　　☐₄ 101 - 500
☐₅ 501 – 1000　　　　☐₆ More than 1,000, Specify number: ____

D4a. Is this an estimate or an actual count?　☐₁ Estimate　☐₂ Actual Count

D3. What do you think about the ESAP requirement that *nonprescription syringes* be limited to no more than 10 per transaction?

    ❑₁ The limit of 10 per transaction is just right

    ❑₂ The limit of 10 per transaction is too many   → *Indicate preferred amount*:_____

    ❑₃ The limit of 10 per transaction is not enough   → *Indicate preferred amount*:_____

Provide additional comments as needed:_____

_____

D4. Which of the following best characterizes your pharmacy's experience since registering with ESAP? *(Check one)*

    ❑₁ No problems attributable to the sale of needles/syringes without a prescription

    ❑₂ Very few problems attributable to the sale of needles/syringes without a prescription

    ❑₃ Some problems attributable to the sale of needles/syringes without a prescription

    ❑₄ Many problems attributable to the sale of needles/syringes without a prescription

D5. Indicate whether or not each of the following incidents have occurred since registering with ESAP *(Check either "Yes" or "No" for each item)*?

❑₁ Yes	❑₂ No	Underage person attempting to buy needles/syringes without prescription
❑₁ Yes	❑₂ No	Verbal or other abuse by persons attempting to buy needles/syringes without prescription
❑₁ Yes	❑₂ No	Increase in the amount of used needles/syringes found on premises
❑₁ Yes	❑₂ No	Increase in the amount of injection drug use on the premises
❑₁ Yes	❑₂ No	Increase in shoplifting or other thefts
❑₁ Yes	❑₂ No	Customer complaints related to sale of non-prescription syringes
❑₁ Yes	❑₂ No	Community opposition to the sale of non-prescription syringes
❑₁ Yes	❑₂ No	Other incident(s): _____

D6. To what extent do you agree or disagree with each of the following statements. (*Check one box for each statement.*)

A. The sale of sterile needles/syringes without a prescription (ESAP) has increased the amount of general sales in my pharmacy by bringing in new customers.

☐₁   ☐₂   ☐₃   ☐₄   ☐₅
Strongly Agree   Agree   Not Sure   Disagree   Strongly Disagree

B. ESAP has increased my ability to provide timely/emergency access to needles and syringes to diabetics and others normally relying on prescriptions to obtain them.

☐₁   ☐₂   ☐₃   ☐₄   ☐₅
Strongly Agree   Agree   Not Sure   Disagree   Strongly Disagree

C. ESAP has increased opportunities to promote safe needle/syringe disposal.

☐₁   ☐₂   ☐₃   ☐₄   ☐₅
Strongly Agree   Agree   Not Sure   Disagree   Strongly Disagree

D. The sale of sterile needles/syringes without a prescription has made other customers in my pharmacy uncomfortable or fearful.

☐₁   ☐₂   ☐₃   ☐₄   ☐₅
Strongly Agree   Agree   Not Sure   Disagree   Strongly Disagree

E. The sale of sterile needles/syringes without a prescription has increased shoplifting in my pharmacy.

☐₁   ☐₂   ☐₃   ☐₄   ☐₅
Strongly Agree   Agree   Not Sure   Disagree   Strongly Disagree

F. Non-prescription sterile needles/syringes should not be sold to people who intend to inject illicit substances with them.

☐₁   ☐₂   ☐₃   ☐₄   ☐₅
Strongly Agree   Agree   Not Sure   Disagree   Strongly Disagree

Section E: Safe Disposal Options

This section asked about your pharmacy's involvement in safe disposal options for hypodermic needles and syringes.

E1. Are you aware of the location(s) of any community syringe disposal sites in your area?
☐₁ No   ☐₁ Yes

     E1A. If Yes, how did you find out about the location of these syringe disposal sites?

_____

_____

E2. How concerned are you about injection drug users leaving used needles/syringes in or around your pharmacy?

- ❑1 Very concerned
- ❑2 Somewhat concerned
- ❑3 Not concerned

E3. Does your pharmacy engage in any of the following activities related to safe syringe disposal? (*Check all that apply*)

- ❑1 Provision of free sharps containers
- ❑2 Syringe disposal drop-box/kiosk
- ❑3 Sale of sharps containers
- ❑4 Acceptance of syringes in personal sharps containers for safe disposal
- ❑5 Acceptance of loose syringes for safe disposal
- ❑6 Distribution of literature relating to safe disposal of syringes (In addition to safety insert)
- ❑7 Counseling to customers about safe syringe disposal
- ❑8 Other: _____

    E3A. If your pharmacy currently does not sell or furnish sharps containers, please indicate why not: _____

_____

_____

Section F: Further Information and Technical Assistance

F1. Please Indicate whether you would like additional information on any of the following topics.(*Check all that apply*)

- ❑1 ESAP-related brochures/materials
- ❑2 Syringe disposal drop-boxes/kiosks
- ❑3 Locations of disposal sites in NYS
- ❑4 Increasing options for accepting used needles/syringes for disposal
- ❑5 Providing literature on safer sex
- ❑6 Distributing/selling personal sharps biohazard containers
- ❑7 Providing counseling to customers on the sexual transmission of blood borne diseases
- ❑8 Selling bleach kits (to clean syringes)
- ❑9 Providing counseling to customers on safer injection practices
- ❑10 Providing referrals to drug abuse treatment

F2. Would you or your staff be interested in participating in a 1 to 2 hour session that would provide more detailed information and answer questions about ESAP?

☐₁ Yes, without CEU's being offered
☐₂ Yes, only if CEU's are offered
☐₃ No

F3. How have staff in your pharmacy learned about ESAP? (*Check all that apply*)

☐₁ Newsletter from a corporate chain   ☐₅ Mailing from NYS Health Dept.
☐₂ Internet   ☐₆ Pharmacy conference(s)
☐₃ Professional literature   ☐₇ Local health/human service providers
☐₄ Training:_____   ☐₈ Other: _____
_____   _____

F4. Has your pharmacy received adequate information/training to properly implement ESAP in your pharmacy?

☐₁ Yes   ☐₂ No

If No, what additional information/training would be helpful?

_____
_____
_____

F5. Do you have any additional comments you would like to add about ESAP?_____

_____
_____
_____

Thank you for completing this survey!

Please return your survey by May 7th in the enclosed postage-paid envelope addressed to:
Dr. Haven Battles
NYSDOH, AIDS Institute
Office of Program Evaluation and Research
Riverview Center, 5th Floor
150 Broadway,
Menands, NY 12204
OR
Fax your completed survey to Dr. Haven Battles at: (518) 402-6813

California State Board of Pharmacy
400 R Street, Suite 4070, Sacramento, CA 95814-6237
Phone (916) 445-5014
Fax (916) 327-6308

STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

August 3, 2005

Richard S. Garfein, PhD, MPH
Associate Professor
Division of International Health & Cross Cultural Medicine,
Department of Family and Preventive Medicine,
University of California San Diego School of Medicine,
9500 Gilman Drive, mailstop 0622
San Diego, CA 92093

Dear Dr. Garfein:

I am pleased to learn that the University of California, San Diego in collaboration with the California Department of Health Services Office of AIDS, is planning to conduct an evaluation of Senate Bill 1159 (Vasconcellos, Statutes of 2004, Chapter 608) that allows local health jurisdictions to legalize nonprescription syringe sales as a means of HIV and hepatitis prevention. I understand that the results of your evaluation will be included in a report to the Governor and Legislature as mandated by this law. I also understand that as a part of your evaluation, you plan to survey a random sample of pharmacists throughout the state regarding their knowledge, attitudes and practices towards over-the-counter syringe sales and other facets of this law.

The California Board of Pharmacy is willing to assist you in your evaluation. First, we can provide you with a statewide list of registered pharmacists and their address of record, which you can use to select subjects for your pharmacist survey. Second, we would be happy to review and provide comments on your survey instrument. And third, we may be able to improve the response rate for your survey by providing you with a cover letter expressing the Board of Pharmacy's endorsement of this study.

This new law, which makes syringes available without a prescription, has many potential direct and indirect influences on public health in California. The Board of Pharmacy is interested in assisting you in your study.

Sincerely,

P. J. Harris

Patricia Harris
Executive Officer
Board of Pharmacy

Attachment 7

N • C • P • I • E

NATIONAL COUNCIL ON PATIENT INFORMATION AND EDUCATION

For Immediate Release
September 23, 2005

Contact: Deborah Davidson
(301) 656- 8565, x 15

3R's for Safe Medicine Use Highlights Risk Communication
NCPIE Coalition works to improve dialogue / promote safe medicine use

Bethesda, MD: Americans spend over $220 billion a year to purchase over 3 billion prescriptions. An additional $177 billion is spent to address problems triggered by those same medications. To help combat the consequences of medication misuse, the National Council on Patient Information and Education (NCPIE), today launched the **3R's for Safe Medicine Use** program.

"Too many times, people misuse medications, either by not following proper use instructions, or not taking them as directed by their physician, nurse practitioner or physician assistant, said Phillip Schneider, NCPIE Chairman. "This misuse often leads to other health problems. That's why NCPIE is launching the **3R's for Safe Medicine Use** program."

A recent increase in media coverage about medication risks and safety may have caused confusion in the minds of some consumers. NCPIE's **3R's for Safe Medicine Use** program encourages consumers to talk to their healthcare providers about the benefits and risks of medicine prescribed for them. "Consumers will be better equipped to make key decisions regarding their health problems and medicines once they have evaluated important information and discussed the key points with their health care professionals," noted Ray Bullman, NCPIE Executive Vice President.

NCPIE's **3R's for Safe Medicine Use** program focuses on the following key safe medicine use messages:

Risk – recognize that all medicines (prescription and nonprescription) have risks as well as benefits; weigh these risks and benefits carefully for every medicine you take.
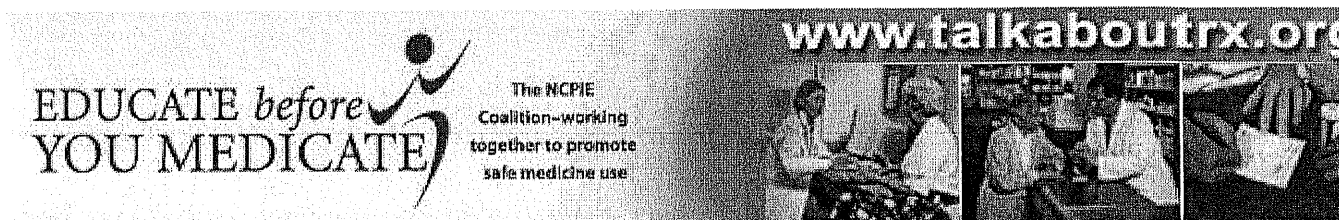
Respect – respect the power of your medicine and the value of medicines properly used.

Responsibility – take responsibility for learning about how to take each medication safely.

Underlying the 3Rs is this important rule -- *when in doubt, ask first.* Your healthcare professional can help you get the facts you need to use medicines correctly.

Launch of the **3R's for Safe Medicine Use** program kicks off **NCPIE's 20th national "Talk About Prescriptions" Month.** Educational materials to support participation in the annual observance are posted on NCPIE's web site www.talkaboutrx.org. Medicine users are also encouraged to make the most of the written consumer medicine information (CMI) leaflet that accompanies each prescription medicine. NCPIE's advice – *"Read it, & Heed It."*

- more -

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together to promote
safe medicine use

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Please consult a
licensed health care
professional with
questions or concerns
about your
medication and/or
condition.

Last Updated
September 23, 2005

"Talk About Prescriptions" Planning Kit for October 2005

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Questions to Ask If Your Medicine Has Been In The
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Message for Health Care Professionals:
"The 3R's for Safe Medicine Use"

Welcome to the 20th annual observance of the National Council on Patient Information
Education's **"Talk About Prescriptions"** Month. This year's theme focuses on the 3Rs
Medicine Use. The 3Rs are **RISK, RESPECT, and RESPONSIBILITY**. For nearly 25 ye
NCPIE has encouraged consumers and patients to ask questions and "get the answers"
their medicines; and we have been suggesting that health care professionals "give the
answers." Such two-way communication - at the point of prescribing and dispensing of
medicines - is vital to promoting patients' ability to get the full benefit from their medic
while using it safely and appropriately. In fact, the American Medical Association (AMA)
input from NCPIE, developed guidelines for physicians for counseling patients about pre
medications, which NCPIE is pleased to share.

Today's technologically-advanced health care practices are implementing computerized
medical records, electronic prescribing, and reaching no further than their personal digi
assistants for up-to-date drug information. Still, for many patients and their caregivers
fashioned talking is their best safety practice when medicines are part of their treatmer
regimen.

What's a great starting point for talking about medicines? The first step is anticipating i
advance patients' concerns and questions about medicines, and in some cases, a reluct
ask questions. A suggestion --use every opportunity to ensure that the patient underst;
to use each medicine safely and appropriately. Also, the consumer medicine informatio
leaflet that is printed out at the pharmacy and provided to patient with their prescriptio
medicine is another opportunity to "Talk About Prescriptions." According to the U.S. Fo
Drug Administration, nine out of 10 consumers receive a CMI leaflet with their medicine
sure to reinforce the useful information on the CMI, including, instructions for use, war
precautions and what to do about side effects.

As part of **"Talk About Prescriptions"** Month, be sure to remind patients and caregiv
the value of the CMI leaflet information. Once patients leave your office and the pharm,
understanding the importance of reading and referring regularly to the CMI information
make the difference between using a medicine safely or, for example, experiencing an
or manageable side effect.

Remember the 3Rs for Safe Medicine Use. Patients look to you for help in understandin use medicines correctly - to avoid harm and to get the most value from their medicine. information - whether oral or written - is good medicine. That's a message worth remei during **"Talk About Prescriptions"** Month, and all year round.

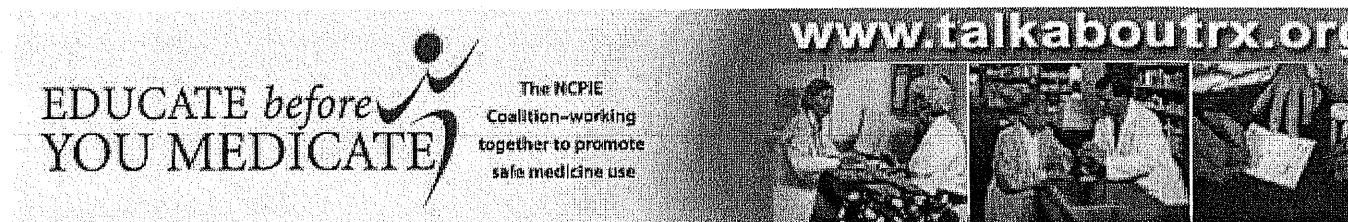Back to **"Talk About Prescriptions"** Planning Kit Page

NCPIE
4915 Saint Elmo Ave., Suite 505
Bethesda, MD 20814-6082

Phone (301) 656-85(
Fax (301) 656-44(
Email ncpie@ncpie.i

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www.talkaboutrx.org

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Please consult a licensed health care professional with questions or concerns about your medication and/or condition.

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September 23, 2005

"Talk About Prescriptions" Planning Kit for October 2005

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Radio Public Service Announceme
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Risk Communication Articles

Questions to Ask When You Get a New Prescription Medicine:

1. What is the name of the medicine and what is it supposed to do?
2. Is this the brand or generic name? (Is a generic version available?)
3. When do I take the medicine - and for how long?
4. Should I take this medicine on an empty stomach or with food?
5. What should I do if I forget a dose?
6. What foods, drinks, medicines, dietary supplements, or activities should I avoid w taking this medicine?
7. What are the possible side effects, and what do I do if they occur?
8. When should I expect the medicine to begin to work, and how will I know if it is w
9. Will this new prescription work safely with the other prescription and non-prescrip medicines I am taking?
10. How should I store this medicine at home?

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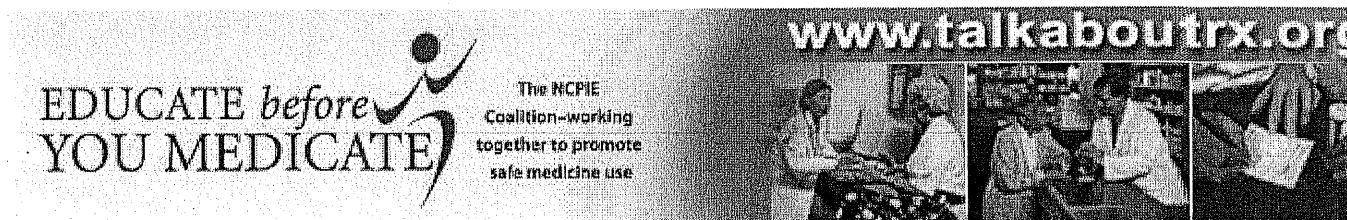4915 Saint Elmo Ave., Suite 505
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The News**

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TAP Poster
Risk Communication Articles

Questions to Ask If Your Medicine Has Been In The News:

1. Do you think the benefits of taking this medicine outweigh the risks?
2. What are the risks associated with taking this medicine?
3. Are there any alternative medicines to the one I am taking?
4. Are there any alternatives to this medicine, such as making lifestyle changes, If y(
   should I try these?
5. What side effects should I look out for and when should I call you about them?
6. In summary, would you review the best course of action for me?
7. Can we set up an appointment in 1 - 3 months to see how I'm doing on the new d

(Source: University of California, San Francisco School of Pharmacy and California Board of Phari
2005)

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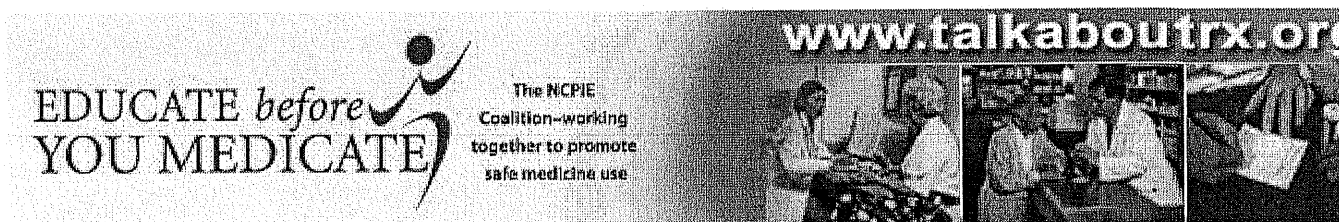4915 Saint Elmo Ave., Suite 505
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Radio Public Service Announcements Scripts:

How to Use

1. Adapt any (or all) of the following "live read" scripts for use on local radio and tele stations.
2. Type each script, double-spaced, on your letterhead. Be sure to include the name contact person from your organization.
3. Submit scripts to radio public service directors in your community as soon as poss
4. Tip -- Also submit the scripts to the weather forecasters at your local television st:
5. Follow up with a phone call 3 - 5 days after submitting the scripts. Verify that the and if broadcasting them during the upcoming season is possible.
6. If the public service director or weather forecaster was receptive to your first phor follow up with additional calls over the next few months to remind him/her of the
7. Send a thank you note to the manager of any radio station or television station th one of your PSAs.

Live-Read Radio Scripts (:30 second scripts)

Script Number 1: ***Read It & Heed It***

Ann: The next time you fill a prescription medicine, be sure you also get written inform about the medicine to read at home. Your medicine is important to your good health. S medicine information. Be sure you read the information carefully and refer to it often w take your medicine. A message from the National Council on Patient Information and E (insert your organization's name) and (insert radio station call letters). Visit www.talkaboutrx.org for details.

Script Number 2: ***What to Watch for***

Ann: Just got a new prescription medicine? Be sure to take it right. Read carefully the information that comes with the medicine. It includes useful information about possible effects, warnings, what other medicines, foods, or drinks to avoid while taking the med and lots more. Your medicine is important. So is your medicine information. A message the National Council on Patient Information and Education, (insert your organization's r

and (insert radio station call letters). Visit www.talkaboutrx.org for details.

Script Number 3: *Celebrate Safe Medicine Use*

Ann: Americans take medicines every day with enormous potential to heal, but that wh improperly, can be harmful. Medicine allows people to lead healthier lives; however tak medicines is not without some level of risk - especially if you're taking four or more diff medicines. This October, celebrate the 20th annual "Talk About Prescriptions" Month ca by making sure you know how to use your medicines safely. For details, contact the Na Council on Patient Information and Education at www.talkaboutrx.org

Script Number 4: *The 3Rs for Safe Medicine Use*

This October marks the 20th annual "Talk About Prescriptions" Month. What can you do participate? *Remember the 3Rs for safe medicine use - risk, respect, and responsibility.* start. Also, take personal responsibility for learning how to take each medication you us A message from (insert name of your organization),the National Council on Patient Info and Education, and (insert radio call letters). Visit www.talkaboutrx.org for details

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About Risk

From: Healthy People 2010 / Focus Area 17 - *Medical Product Safety*

See: http://www.healthypeople.gov/Publications/

Medical products—which include drugs, biological products, and medical devices—provide great public benefit. Although marketed medical products are required to be safe, this safety requirement does not mean they have zero risk. A safe product has reasonable risks, given the magnitude of the benefit expected from the product and the alternatives to its use. Thus the choice to use a medical product involves balancing its benefits with the potential risks of using it. The comparative evaluation—which involves weighing the benefits (positive effects) and risks (potential harm) of various medical options for treatment, prophylaxis, prevention, or diagnosis—is an essential part of determining product safety. Evaluation is done during research and development on new medical products or procedures (such as surgery) or by a regulatory authority deliberating the approval or withdrawal of a product or some intermediate action, by a physician on behalf of a patient, or by the patient. Such weighing, whether implicit or explicit, is at the heart of decision-making in medicine and health care.

Sources of risk. It is widely accepted that enormous benefits can be gained from using medical products. Yet while most are well tolerated, producing only minimal side effects or a low rate of adverse events, some products can be very toxic, producing a high rate of complications from side effects.[1] It is estimated that millions of adverse events associated with the use of medical products occur each year; many of these are serious and may result in death.[2] Federal oversight of a medical product's benefits versus risks continues well beyond the initial marketing of a product. Once a medical product is approved for marketing, the safety of the product continues to be monitored by FDA, which collects and analyzes reports of product experience. As more products are approved for marketing, postmarketing surveillance becomes increasingly important.

Through a program called MEDWATCH, FDA's Medical Products Reporting and Safety Information Program, health care professionals, patients, and consumers can report serious adverse events and problems associated with medical products to FDA, the manufacturer, or both. MEDWATCH also accepts reports of medication errors or potential errors. MEDWATCH partners include health professionals, consumers, and other appropriate health-related organizations or commercial interests that actively disseminate information on the critical importance of monitoring and reporting serious adverse events and product problems, along with information on how to report directly to FDA. These partners also provide a multiplier effect, by which MEDWATCH partners rapidly disseminate new FDA-related product safety information back to their membership.

Beyond the individual level of risk management (for example, patients and health care providers), managing risk must be targeted at the organization level. For example, user facilities such as hospitals, long-term care facilities, ambulatory surgical, outpatient treatment, and outpatient diagnostic centers are required to report errors related to medical devices. By law, these facilities are required to report any death to FDA and to the manufacturer of the device within 10 working days. Any serious illness or injury also must be reported by the user facility to the manufacturer within 10 working days, or, if the manufacturer is unknown, the report should be sent to FDA. Further, FDA encourages user facilities to report product or device malfunctions (for example, intravenous catheter defects) that do not result in death or serious injury directly to the manufacturer.

Management of medical product risk. In general, the sources of medical product risks can be thought of as falling into four categories: (1) product defects, (2) known side effects, both avoidable and unavoidable, (3) medication or device errors, and (4) remaining uncertainties.[3] Because each type of risk

has a different source, effective management of each is likely to be different:

Product defects. Historically, product defects have been an important source of medical product-associated injuries. In the case of pharmaceuticals, product defects usually include the lack of potency and the lack of purity of drugs. A significant portion of resources currently is devoted to regulating product quality. Research, surveillance, quality systems also called *current good manufacturing practices*, and inspections form the cornerstone of FDA efforts to minimize product defects.

Known side effects. When using a drug or other medical product, a patient runs the risk of experiencing reactions resulting from the product's interaction with the body. For pharmaceuticals, these reactions are commonly termed *side effects*. They usually are identified in a product's package insert as possible risks. Known side effects are the source of the majority of injuries and deaths resulting from product use.

Some known side effects often are predictable and avoidable. To avoid them, the health care practitioner must select the best treatment and plan appropriate measures to manage the risks to the patient. For example, when prescribing certain prescription medications that are renal toxic (toxic to the kidneys), practitioners need to ensure that their patients are well hydrated or calculate dose adjustments to reduce the risk of toxicity or kidney failure. A medical practitioner can choose the wrong therapy for a specific condition (for example, using antibiotics for viral infections). Alternatively, a practitioner may prescribe the appropriate therapy but fail to individualize the therapy or monitor the patient for signs of toxicity. Examples of avoidable side effects include the consequences of known drug-drug interactions or prescribing an inappropriate dosage for elderly persons.

In many cases, known side effects are unavoidable because they can occur even if a product is used appropriately. Although estimates vary, the overall human and economic costs of unavoidable side effects are high.[4] The risk of experiencing such side effects is the inevitable price of the benefits of treatment. Examples of common, predictable, usually unavoidable side effects include superinfection following antimicrobial chemotherapy, fatigue and depression from interferon use, and bone marrow suppression from chemotherapy. For the successful management of these risks, both the practitioner and patient must be fully aware of the risks involved in treatment, agree to the treatment, and provide careful patient monitoring to detect early symptoms of known side effects.

Medication or device errors. A medication or device error involves the incorrect use of a prescribed product or incorrect operation or placement of a medical device. Errors also involve unintended substitution of the wrong product for the prescribed product. Errors can occur, for example, when a confusing product name results in the wrong product being dispensed or when inattention results in an overdose of an intended drug. Substantial numbers of injuries and deaths occur annually because of medication or device errors.[5] In general, medication and device errors are believed to result from problems intrinsic to the health care system. That is, these errors often are the result of a sequence of errors within the health care system. For example, a physician's poor handwriting on the prescription pad and unclear or confusing prescription drug labeling result in pharmacists' misreading prescriptions and labeling and filling prescriptions with the wrong medications. Such errors are not totally preventable, but they can be minimized through enhancements aimed at integrating the overall health care system.

Remaining uncertainties. Given current scientific and medical knowledge, it is not possible to learn everything about the effects of a medical product. For example, new information about long-marketed products may become available. Therefore, a degree of uncertainty always exists about both the benefits and risks of medical products, including unexpected side effects, long-term effects, effects of off-label use, and effects in populations not studied before marketing.

Managing risk and medical product safety is a matter of continuously developing information. A comprehensive risk management system requires risk communication. Thus, effective risk communication demands that risk information be translated into words and formats that are readily understood by practitioners, caregivers, and patients.

For example, U.S. Pharmacopeia (USP) and FDA have adopted the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) Taxonomy for Medication Errors in order to report, track, and benchmark medication error data in a standardized format for hospitals nationwide. In this risk communication strategy, FDA and USP are expected to provide a nationally projected measure of errors grouped according to categories established by the NCC MERP.

Disparities

Certain groups are particularly vulnerable to poor health outcomes because they are exposed to both socioeconomic and age-related physiological stress factors that interact synergistically. **People aged 65 years and older**, for example, take the greatest number and quantity of medications.[6] Of elderly patients taking three or more prescription drugs for chronic conditions, more than one-third are re-hospitalized within 6 months of discharge from a hospital, with 20 percent of those re-admissions due to drug problems.[7] Twenty-eight percent of hospitalizations of older people are due to noncompliance with drug therapy and adverse events.[8] Adverse drug events rank fifth among the top preventable threats to the health of older people in the United States, after congestive heart failure, breast cancer, hypertension, and pneumonia.[9] Moreover, 32,000 adults aged 65 years and older suffer hip fractures each year as a result of falls associated with the use of psychotropic drugs, which are used to treat the patients' underlying medical condition.[10] A growth in these numbers is expected, given the increasing number and potency of drug products being marketed and the increasing percentage of the population that are elderly.

Another example of a common variable that predisposes individuals to vulnerability and poor health outcomes is **literacy.** Literacy disparities are of concern because low-literacy patients cannot be "empowered" consumers.[11] Further, patients who do not understand health professionals' instructions will not receive good-quality care. Finally, because health literacy problems are concentrated in populations that depend on public programs for their medical care, an education effort may be required to inform public assistance patients about how to understand the proper use of their medicines. To reach all people effectively, information must be provided in a variety of formats and reading levels. (See Healthy People 2010, Focus Area 7. Educational and Community-Based Programs, and Focus Area 11. Health Communication).

Footnotes:

1. Lazarou, J.H; Pomeranz, B.; and Corey, P.N. Incidence of adverse drug reactions in hospitalized patients. A meta-analysis of prospective studies. *Journal of the American Medical Association* 279(15):1200-1205, 1998.

2. Institute of Medicine. *To Err Is Human: Building a Safer Health System.* Kohn, L.T., ed. Washington, DC: National Academy Press, 1999.

3. Food and Drug Administration (FDA) Task Force on Risk Management. *Managing the Risks from Medical Product Use: Creating a Risk Management Framework.* Rockville, MD: FDA, May 1999.

4. Johnson, J.A., and Bootan, L.J. Drug-related morbidity and mortality: A cost-of-illness model. *Archives of Internal Medicine* 155:1949-1956, 1995.

5. Bates, D.W.; Cullen, D.J.; Laird, N.; et al. Incidence of adverse drug events and potential adverse drug events: Implications for prevention. *Journal of the American Medical Association* 274:29-34,1995.

6. U.S. General Accounting Office (GAO). *Prescription Drugs and the Elderly.* AO/HEHS-95-152. Washington, DC: GAO, 1995.

7. Bero, L.A.; Lipton, H.L.; and Bird, J.A. Characterization of geriatric drug-related hospital readmissions. *Medical Care* 29(10):989-1003, 1991.

8. Col, N.; Fanale, J.E.; and Kronholm, P. The role of medication noncompliance and adverse drug reactions in hospitalizations of the elderly. *Archives of Internal Medicine* 150(4):841-845, 1990.

9. Fink, A.; Siu, A.L.; Brook, R.H.; et al. Assuring the quality of health care for older persons. An expert panel's priorities. *Journal of the American Medical Association* 258(14):1905-1908, 1987.

10. Ray, W.A.; Griffin, M.R.; Schaffner, W.; et al. Psychotropic drug use and the risk of hip fracture. *New England Journal of Medicine* 316(7):363-369, 1987.

11. Ad Hoc Committee on Health Literacy for the Council on Scientific Affairs, American Medical Association. Health literacy: Report of the Council on Scientific Affairs. *Journal of the American Medical Association* 281(6):552-557, 1999.

RETAIL PHARMACY SALES FOR 12 MONTHS ENDED JULY 2005 RISE 5 PERCENT IN KEY
GLOBAL
MARKETS

--

Drug sales through retail pharmacies in 13 key markets rose 5 percent to
$361.6 billion from August 2004 to July 2005 at a constant exchange rate,
according to IMS Health Inc.'s Retail Drug Monitor. The 12-month increase
reported last month was 6 percent.

For the 12-month period ended July 2004, retail pharmacy drug sales totaled
$335.78 billion.

U.S. retail drug sales grew 6 percent to $179.76 billion, led by $41.35
billion in sales of central nervous system drugs. In the United States and
Canada, the key therapeutic growth area was cardiovascular drugs; sales in
this category increased 10 percent at constant exchange, a slight decrease
from last month's reported figures.

Sales growth rates (also at constant exchange) in the top five European
markets, the top three Latin American markets and Japan were 3 percent, 17
percent and 4 percent, respectively, compared with last month's increases of
4 percent, 16 percent and 3 percent.

Pfizer Inc.'s cholesterol-lowering drug, Lipitor (atorvastatin calcium), was
the best-selling drug, with global sales totaling more than $11.09 billion,
although its sales growth decreased to 10.8 percent. Bristol-Myers Squibb Co.
and sanofi-aventis Group's thrombosis treatment, Plavix (clopidogrel
bisulfate), experienced the highest rate of growth, at 22 percent.
-=-
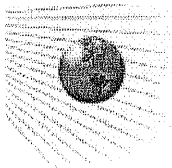
Jan Perez
09/15/2005 12:30 PM

To: joshua.room@doj.ca.gov, Dana Winterrowd/EXEC/DCANotes@DCANotes, Patricia Harris/Pharmacy/DCANotes@DCANotes, Virginia Herold/Pharmacy/DCANotes@DCANotes
cc:
Subject: Press Clips - Thursday, September 15, 2005

Health Affairs Reports Discuss Barriers, Advantages, Costs of Implementing Health Information Technology Systems

Several newspapers on Thursday addressed three studies and one editorial on health care information technology published Wednesday in the September/October edition of Health Affairs. Summaries appear below.

*Cost Effectiveness: Implementation of a nationwide electronic health records network would take about 15 years and cost
hospitals about $98 billion and physicians about $17 billion, according to a study by Richard Hillestad and colleagues at
RAND, the AP/Las Vegas Sun reports (Neergaard, AP/Las Vegas Sun, 9/14). Over the 15-year period, the average annual cost to hospitals would be $6.5 billion and the average annual cost to physicians would be $1.1 billion (CQ HealthBeat [1], 9/14). However, if 90% of providers adopted such a network, annual savings would total $81 billion, including $77 billion from improved efficiency and $4 billion from reduced medical errors, the study found (AP/Las Vegas Sun, 9/14). The study estimates that an EHR network would reduce adverse drug events in inpatient hospital settings by 200,000 annually and reduce such events in ambulatory settings by two million annually, saving $1 billion annually in hospitals and $3.5 billion in ambulatory settings. For hospitals, about 60% of these savings would be from reduced adverse drug events in patients ages 65 and older, while 40% of savings to ambulatory practices from reduced medication errors would be in patients 65 and older (CQ HealthBeat [1], 9/14). In addition, the study estimates that a national EHR network would save Medicare about $23 billion annually and save private insurers about $31 billion annually. The study projects that the estimated total annual savings of $81 billion would double if providers followed all checkup reminders and other prompts from the system (AP/Las Vegas Sun, 9/14). Currently, about 20% to 25% of hospitals and 15% to 20% of physician offices have EHR systems, according to the study (CQ HealthBeat [1], 9/14). An abstract of the study is available online.

*Editorial: RAND's projections are based on "a disturbing array of unproven assumptions [and] wishful thinking," David
Himmelstein and Steffie Woolhandler of Harvard Medical School write in a commentary piece accompanying the RAND study (AP/Las Vegas Sun, 9/14). Although EHR technology has progressed over the past three decades, "computers don't offer the panaceas that politicians hope for and computer firms are peddling," they wrote (Trehan, Reuters/Boston Globe, 9/15). An abstract of the commentary is available online. Small Practices: Physician practices spent an average of about $44,000 per full-time equivalent provider to implement an EHR system and about $8,500 per provider to maintain the system, according to a study of 14 solo and small group practices with EHR systems. On average, the practices recouped the costs of the systems through business savings within two and a half years, although "some practices
didn't recoup the investments for years," the AP/Sun reports. The study was led by researchers at the University of
California-San Francisco (AP/Las Vegas Sun, 9/14). An abstract of the study is available online.

*Group Practices: About 14.1% of group practices use an EHR system, according to a nationwide survey conducted by
researchers at the Medical Group Management Association Center for Research and the University of Minnesota School of Public Health and funded by the Agency for Healthcare Research and Quality. The percentage of practices with EHR systems increased as the size of the group practices increased, the survey found. About 12.5% of practices with five or fewer full-time equivalent physicians reported use of an EHR system, compared with 15.2% for practices with six to 10 FTE physicians, 18.9% for practices with 11 to 20 FTE physicians and 19.5% for groups with 20 or more FTE physicians, according to the survey. The average cost of purchasing and implementing an EHR system was $32,606 per FTE physician, with monthly maintenance costs of $1,500 per FTE physician, the survey found. In addition, the average cost of
EHR system implementation was about 25% higher than initial vendor estimates, the survey found (CQ HealthBeat [2], 9/14). An abstract of the study is available online.

NCQA Opens Public Comment Period

In related news, the National Committee for Quality Assurance will be accepting public comment on its Physician Practice
Connection program until Oct. 11, CQ HealthBeat reports. The program recognizes physicians who use health care IT in their practices. It includes 80 practices representing 700 physicians (CQ HealthBeat [3], 9/14).

Broadcast Coverage

APM's "Marketplace" on Wednesday reported on the studies. The segment includes comments from Hillestad; Robert Miller, a health economist at the University of California-San Francisco; and Woolhandler (Palmer, "Marketplace," APM, 9/14). The complete segment is available online in RealPlayer.

http://www.kaisernetwork.org/daily_reports/rep_index.cfm?DR_ID=32587

U.S. generic drug prices are lower than Canada's

WASHINGTON – Mabel Stoltz, at 93, lives independently in her own home in a quiet harbor town on the Minnesota shore of Lake Superior.

But she has to watch her budget carefully and is buying prescription drugs from Canada.

So Stoltz was surprised to learn recently that she could buy her generic-label medications for much less from a U.S. pharmacy – a potential savings of $560 a year for two prescriptions. "I do have enough money to pay, but I don't know how long it will last at this rate," said Stoltz, who once worked as a medical secretary.

Like Stoltz, many U.S. consumers have been buying generic drugs from Canada, not realizing that generics – unlike brand-name medications – are usually quite a bit less expensive at home. U.S. consumers might be wasting more than $100 million a year on Canadian generics, according to one Canadian analyst, although no firm figures exist on how much Americans are overpaying.

Generic drugs are the therapeutic equivalent of brand-name medications, at about one-quarter of the cost. Generic versions can be marketed after the patent protection on a brand-name drug expires.

U.S. residents know brand-name drugs are less expensive in Canada because of government price controls there. But many don't realize that Canadian policies have the opposite effect on prices for generic drugs.

Brett Skinner, director of pharmaceutical and health policy research for the Fraser Institute in Toronto, said the Canadian government's policies work against makers of generic drugs. The public policy organization advocates free-market policies, including the repeal of price controls on brand-name drugs.

Earlier this year, the institute released a study by Skinner of the 100 top-selling generic drugs. It found that Canadian prices were, on average, 78 percent higher than in the United States. The study estimated that Canadians could save $2 billion to $5 billion annually if their generic market were as competitive as that in the United States. (The study accounted for exchange rate differences, and the potential savings are in Canadian dollars.)

A smaller study last year for the U.S. Department of Health and Human Services looked at five popular generics and found U.S. prices were 32 percent lower.

Canadian drug-approval regulations make it difficult for foreign generic competitors to enter the market, Skinner said, and the reimbursement policies of Canada's provincial governments act to keep prices artificially high.

"We have very few companies competing for sales – two companies take up nearly 70 percent of the market for the top 100 drugs," he said.

Generic drugs are less expensive in the U.S. because more manufacturers are competing in the market, said Tom McGinnis, director of pharmacy services for the Food and Drug Administration. Shipping charges also can widen the difference.

Jan Perez

09/14/2005 11:22 AM

To: joshua.room@doj.ca.gov, Dana
Winterrowd/EXEC/DCANotes@DCANotes, Patricia
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Herold/Pharmacy/DCANotes@DCANotes

cc:

Subject: News Clips - Wednesday, September 14, 2005

HHS Moving Forward With Computerization of Hurricane Survivors' Medical Records; Leavitt Names Members of Task Force To Oversee Implementation of Nationwide System

Medical personnel who have treated Hurricane Katrina evacuees in eight shelters on Tuesday began to use an online federal database of prescription drug records provided by retail pharmacies, the Washington Post reports. The database, in development for about 10 days, includes prescription information for more than 800,000 individuals located in 150 ZIP codes affected by the hurricane. The database includes prescription drug records from CVS, Rite Aid, Albertsons, Walgreen and Wal-Mart, with records from Winn-Dixie, Kmart and Target expected in the near future. Federal officials also hope to add to the database electronic health records from pharmacy benefit managers, laboratories, Department of Veterans Affairs health facilities, and the Mississippi and Louisiana Medicaid programs.

Federal Requirements Suspended

According to the Post, the case marks the first in which the federal government has used private health records from
retailers to compile an electronic database. Although patient consent is not required when health records are shared for
medical purposes, companies and organizations that possess such records must reach formal agreements before they can share the information with each other. However, federal officials said that they would not enforce the formal agreement requirement in this case, provided that the companies and organizations reach verbal agreements to use the health records to help hurricane evacuees. According to National Coordinator for Health Information Technology David Brailer, who has overseen the development of the database, only medical personnel at hurricane shelters and hospitals that treat hurricane evacuees will have access to the health records. Brailer said, "We've been extremely cautious." Sue Blevins, founder of the Institute for Health Freedom, said that she supports the database in this case but added that "many things are done during a crisis that society normally would not accept."

Future Use?

The database currently allows medical personnel to access the health records of hurricane evacuees, but they cannot add new information. Brailer said that the federal government had planned to discontinue the database after hurricane relief
efforts are complete. However, others involved with the database "already are discussing ways to enhance the system and create personal health records for those who might need to move frequently over the next several months," the Post reports. Ray Fowler, director of a hurricane relief operation in Dallas, said, "We're already preparing for a second wave of victims who have been in hotels but the money is running out" (Krim, Washington Post, 9/14).

http://www.kaisernetwork.org/daily_reports/rep_index.cfm?DR_ID=32552

ll Street Journal Examines Legal Fights Over Online Physician Reviews

The Wall Street Journal on Wednesday examined the "growing number of legal battles being waged over Internet postings about medical complaints." According to the Journal, many patients have begun to post reviews of physicians on the Internet, a practice that "has some medical providers on edge." Several Web sites encourage patients to post anonymous reviews of physicians and dentists. For example, the Web site nddb.net asks patients to review thousands of physicians, and the site has collected about 600 responses to date. DR.Oogle administers a free Web site that includes anonymous reviews of about 19,000 dentists, and ratemds.com, also a free site, features about 11,000 reviews of physicians and allows physicians and others to post rebuttals. In addition, some patients have launched Web sites that criticize specific physicians. In response, some physicians have filed lawsuits against patients and Web site operators. "The potential problems are huge. My reputation is my stock in trade, ... and we work years and years to build that reputation. To have that shattered potentially (by an Internet posting) is a concern," Matt Messina, a dentist in Ohio and a spokesperson for the American Dental Association, said. Patient advocates, however, maintain that patients have a First Amendment right to describe their experiences with physicians. Lawrence Hipshman, an Oregon psychiatrist and professor at Oregon Health and Science University who received a single, negative review on nddb.net, said, "There shouldn't be any attempt to create a profile until there are maybe 100 reviews on a person" (Kesmodel, Wall Street Journal, 9/14).

http://www.kaisernetwork.org/daily_reports/rep_index.cfm?DR_ID=32555

Wall Street Journal Examines Issues Surrounding New Medicare Prescription Drug Benefit

The Wall Street Journal on Wednesday examined issues related to the launch of the new Medicare prescription drug benefit and the advice provided to beneficiaries. According to the latest government estimates, between 11 and 23 different companies -- ranging from national health insurers such as Humana to small regional providers -- will offer stand-alone drug benefits to beneficiaries, depending on where they live. Enrollment in the new benefit will begin Nov. 15, and CMS in mid-October is planning to launch a Web site that will help beneficiaries choose a plan. However, some health policy experts continue to express concern about the number of choices seniors will face. "The question is: Will seniors be so overwhelmed by all these choices that they throw up their hands and say, 'Forget about it'?" Tricia Neuman, a Kaiser Family Foundation vice president and director of its Medicare Policy Project, said. According to the Journal, beneficiaries considering enrolling in a Medicare drug plan should consider a number of factors, such as timing -- there will be financial penalties for beneficiaries who enroll after the May 15 deadline -- and costs, including deductibles, premiums and copayments that will vary by plan. The Journal also recommended that beneficiaries find out whether former employers will continue to provide retiree prescription drug benefits and whether alternatives such as Medicare Advantage plans or Medigap provide superior coverage to stand-alone PDPs (Lueck, Wall Street Journal, 9/14).

http://www.kaisernetwork.org/daily_reports/rep_index.cfm?DR_ID=32559

"California HealthCare
Foundation"
<info@chcf.org>

10/07/2005 01:06 AM

To: <virginia_herold@dca.ca.gov>
cc:
Subject: Millions Pour Into Campaign Coffers

<u>HealthVote.org</u>

**Project
Partners**

[IMAGE]

[IMAGE]

<u>Visit
HealthV
ote.org</u>

[IMAGE]

October 7, 2005

Millions of Dollars Collected For and Against Propositions 78
& 79

Prop. 73 Proponents and Opponents
Relatively Quiet on Money Front

With a month to go until the Special Election, the most recent
campaign finance data from the California Secretary of State's
Office shows major investments by pharmaceutical companies
in support of Proposition 78 and against Proposition 79. As of
September 29, <u>Prop. 78 proponents</u> have amassed more than
$80 million and spent $46.4 million. Meanwhile, <u>proponents of
Prop. 79</u> have raised an estimated $1.8 million – with nearly all
of their funds to date spent on qualifying the initiative for the
ballot.

In contrast, the war chests of <u>advocates and opponents of
Proposition 73,</u> a measure to require parental notification on
abortion, are more evenly matched. Prop. 73 proponents have
raised $1.2 million as of September 29, while opponents
collected $1.7 million. Both sides have spent $1.1 million –
with proponents spending almost all of their funds to qualify
the initiative for the ballot.

Who's Contributing?
In terms of dollars, the top ten contributors for and against
Prop. 73 are split evenly between individual donors ($1.1
million) and organizational donors ($1.2 million). However,
while the ten largest donors for Prop. 73 are individuals, most
(92%) "No on 73" funding has been contributed by
organizations. For more details on donors and dollars, visit
<u>Prop. 73 MoneyWatch</u>.

The top ten contributors in support of Prop. 78 are
pharmaceutical companies, which have donated $75.8 million
(of the $80.1 million total) in support of the measure. To date,

no contributions from individuals have been made toward Prop. 78. Just six percent of financing is derived from California based companies, with 94 percent coming from out-of-state. For more on dollars and donors, visit Prop. 78 MoneyWatch.

The top ten contributors in support of Prop. 79 (estimated as one-sixth of total contributions to Alliance for a Better California, a coalition of organizations raising money for Props. 79 and 80, and against Props. 74, 75, 76 and 78) are California-based organizations. Unions and teachers' associations make up the majority of contributors to the Alliance for a Better California, the sponsor of Prop. 79. For more on dollars and donors, visit Prop. 79 MoneyWatch.

Can History Predict the Future?
Past results show that when opponents dramatically outspend proponents in California ballot measure campaigns, these measures tend to be defeated. Money spent against a ballot measure has historically been much more effective than money spent in favor of a measure.

However, heavily out-spent initiative proponents do not always lose. In 1988, for example, voters passed large insurance rate rollbacks with Prop. 103, despite $80 million that insurance companies spent against the measure. In addition, the insurance industry put three other initiatives on the ballot to compete with and dilute support for Prop. 103. Only Prop. 103 won, and its proponents succeeded with less than $4 million. For a more detailed analysis of the California initiative process and the impact of campaign contributions, read the article "Democracy by Initiative: Shaping California's Fourth Branch of Government" at HealthVote.org.

Recent poll results show diminishing support for both prescription drug measures, but earlier Field Poll results indicate that voter support increases for Prop. 79 when pollsters mention that consumer groups support the measure. Also, support for Prop. 78 declines when pollsters mention that pharmaceutical companies support the measure.

Visit HealthVote.org for frequently updated information on campaign finance data, television advertising and non-partisan analysis of the health-related initiatives. HealthVote.org, created by the California HealthCare Foundation and the Center for Governmental Studies, provides voters with facts

and non-partisan analysis, as well as easy access to information on who supports and opposes the measures, who is paying for the campaigns, how much is being spent, results of statewide polls, and the latest news.

The Center for Governmental Studies and the California HealthCare Foundation have partnered to provide you with unbiased information on each of the three health measures on California's November ballot. To unsubscribe from this list or to forward to a friend, see below.

Federal Health Officials Working To Computerize Medical Records of Hurricane Survivors; Experience Demonstrates Need for Nationwide Electronic Records System, Leavitt Says

HHS officials are using electronic health records systems to compile and monitor prescription and treatment histories for
Hurricane Katrina evacuees, HHS Secretary Mike Leavitt said Monday, the AP/Las Vegas Sun reports. Leavitt said the agency is using electronic prescription drug records from retail pharmacies and pharmacy benefit managers to compile a database containing evacuees' prescription drug histories. Evacuees who filled prescriptions at large retail pharmacy chains as much as 90 days before the hurricane should be able to access their prescription records through the database, which is still under development. HHS also is using a pilot EHR program at some shelters, including the Astrodome in Houston, to track evacuees' medical care since the hurricane. At the Astrodome, health care providers can use the EHR system to communicate laboratory results to offsite facilities for analysis.

Recovery Efforts

Copies of EHRs for 50,000 patients treated at the New Orleans Veterans Affairs Medical Center were airlifted to Houston, where they were accessible about four days after the hurricane. Elsewhere, providers are attempting to reconstruct patients' treatment histories from anecdotal accounts, the AP/Sun reports. For example, Joseph Mirro, chief medical officer at St. Jude Children's Research Hospital in Memphis, Tenn., spoke with parents and oncologists to determine chemotherapy regiments for 80 children with cancer who had been evacuated from the Gulf Coast. Leavitt stressed the benefits of EHRs in catastrophes such as natural disasters, saying, "There may not have been an experience that demonstrates, for me or the country, more powerfully the need for electronic health records ... than Katrina." He added that reassembling evacuees' health records "is not going to be a short-term problem" (Neergaard, AP/Las Vegas Sun, 9/13).

Broadcast Coverage

NPR's "Morning Edition" on Tuesday reported on federal health officials' efforts to computerize the medical records of
hurricane survivors and the need for a nationwide EHR system. According to NPR, although the federal government seeks to establish a nationwide EHR system within the next decade, it is currently "so expensive" that few physician offices -- including those "in Katrina's path" -- currently use EMRs, so evacuees must reconstruct their medical history "as best they can" (Montagne/Stamberg, "Morning Edition," NPR, 9/13).

The complete segment is available online in RealPlayer.

http://www.kaisernetwork.org/daily_reports/rep_index.cfm?DR_ID=32530

Many Adults Do Not Follow Doctors' Recommendations for Care, Survey Shows

More than half of U.S. adults have previously decided not to follow treatment recommendations from their physician because they considered them "unnecessary or too aggressive," according to a Wall Street Journal Online/Harris Interactive poll, the Wall Street Journal reports. According to the online poll, which surveyed 2,286 adults nationwide between Aug. 31 and Sept. 2, 83% of respondents said that undertreatment often or sometimes can result in medical problems among patients, and 72% said that overtreatment can contribute to problems. Thirty-two percent of respondents said that they previously have not filled prescriptions they considered unnecessary, the poll found. In addition, 16% of respondents said that they previously have not undergone recommended diagnostic tests they considered unnecessary, and 10% said that they previously have not undergone recommended surgical procedures, according to the poll. The poll also found that almost one-fourth of respondents said they previously have sought a second opinion because they considered treatment recommendations from their physician unnecessary. Poll respondents cited as the main reasons for
unnecessary treatment recommendations physicians' concerns about malpractice lawsuits (53%), physicians' desire to earn more (45%) and physicians' desire to meet the demands of patients (45%). Thirty percent of respondents cited misleading information from pharmaceutical and medical device companies. Katherine Binns, senior vice president at Harris Interactive, said, "A great deal of attention has been given to public concerns about aggressive profiteering on the part of pharmaceutical companies and other sectors of the health care industry," adding that "these findings suggest that to some extent the public is also leery of the motivations behind physicians' decisions regarding patient care" (Bright, Wall Street Journal, 9/13).

http://www.kaisernetwork.org/daily_reports/rep_index.cfm?DR_ID=32531

HHS Uses Electronic Health Records Systems To Help Hurricane Katrina Evacuees

HHS officials are using electronic health records systems to compile and monitor prescription and treatment histories for Hurricane Katrina evacuees, HHS Secretary Mike Leavitt said Monday, the <i>AP/Las Vegas Sun</i> reports.

http://www.californiahealthline.org/track/url.cfm?u=28256&rurl=www%2Ecaliforniahealthline%2Eorg%2Findex%2Ecfm%3FAction%3DdspItem%26itemID%3D114646%26classCD%3DCL421

Bill aims to limit ads for prescription drugs
By Anita Weier
The Capital Times – Madison WI
September 14, 2005

A bill that would prohibit some advertising for prescription drugs received a hearing Tuesday in the State Capitol. The bill would not apply to consumer ads originating outside Wisconsin or ads sent to pharmacists or doctors. Sponsors of the bill say that the sharply rising cost of prescription drugs poses a serious threat to the health of Wisconsin residents, and that advertising directed to consumers aggravates the threat by adding considerable cost to drugs. "The Legislature finds that prescription drug advertising that is directed to consumers is inherently misleading, in that it promotes the sale of products so dangerous that state law does not permit consumers to independently purchase," the bill states. At least 21 legislators have signed onto the bill, authored by Rep. Gary Sherman, D-Port Wing. Sherman told the Assembly Health Committee Tuesday that he tried to draft the bill as narrowly as possible to avoid clashing with the interstate commerce clause of the U.S. Constitution. "We are not going to regulate ads in national magazines or on television," Sherman said. Regarding constitutional concerns about free speech, he pointed out that attorney advertising is heavily regulated in a number of states and that the tobacco industry also is regulated. "We are only interested in commercial speech, not informational speech," Sherman said. "Thirty-second commercials are not informative." "All of the drugs withdrawn from the market recently have been heavily advertised," he contended. But Peter Fox, a representative of

the Wisconsin Newspaper Association, said the proposal does have constitutional flaws, because it would be impossible to distinguish between in-state and out-of-state ads. "How would you react to a Wisconsin newspaper that had an insert in Parade magazine with an ad?" Fox asked. "You would put Wisconsin publishers and broadcasters in an untenable situation. "This is a public policy question," Fox said . "The appropriate place to address it is in Congress and federal agencies." Mark Grapentine, speaking for the Wisconsin Medical Society, conceded that patients who see an ad might ask a doctor why he or she did not give them that drug. But someone might tell their doctor that they think they have a certain condition because of an ad, and sometimes they might in fact have that condition, Grapentine said. "Physicians believe there can be benefits," he said. "This is too much of a sledgehammer." Rep. Gregg Underheim, R-Oshkosh, the committee chairman, asked whether the WMS position was that doctors occasionally misdiagnose and TV commercials help patients diagnose their own symptoms. Grapentine responded that the best way to be diagnosed is to talk to your own doctor, though "physicians are not perfect" and the Internet sometimes provides valuable information. Representatives of PhRMA, the Pharmaceutical Research and Manufacturers of America, opposed the bill. "We know that Direct to Consumer communications, particularly DTC television advertising, can be a powerful tool for reaching and educating millions of people, and we are committed to ensuring that our DTC communications provide accurate, accessible and useful health information to patents and consumers," the pharmaceutical industry association said in a written statement.

http://www.madison.com/tct/news/stories/index.php?ntid=54071&ntpid=2

Staying The Course: New gee-whiz technologies are improving patients'
compliance with their drug regimens.
By: Carol Ukens
Drug Topics
Sep 12, 2005

Patients who don't take their medications or who take them improperly are a
plague on healthcare systems around the world. The World Health
Organization estimates that adherence to long-term therapy for chronic
conditions averages about 50% in industrialized countries, and it's even
worse in developing countries. Studies have shown that when prescriptions
are written, one-third of patients take the medications as prescribed,
one-third take some of the medicine, and one-third don't even bother to
fill the prescription. Since 65% of adults in a recent Harris Interactive
poll said they forgot to take their medications, developing devices that
jog patients' memories has been an obvious point of attack on
noncompliance. Recognizing the limitations of the little plastic pillbox
and human nature, some enterprising folks have built a better compliance
mousetrap. Drug Topics decided to take a look at some of the ones that have
literally added bells and whistles to alert patients when it's time to take
their next dose of medicine.

http://www.drugtopics.com/drugtopics/article/articleDetail.jsp?id=179333&page
ID=1&sk
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Several people in a public hearing on Wednesday testified that a Rhode Island Health Department proposal requiring Canadian pharmacies to purchase $5 million in product liability insurance to obtain a pharmacy license is too strict and could "undermine" the state law granting Canadian pharmacies state licenses, the Providence Journal reports (Freyer, Providence Journal, 6/16). The law, passed in July 2004, is the first in the nation in which a state plans to grant pharmacy licenses to Canadian pharmacies. Draft rules proposed by the Rhode Island Department of Health would require Canadian pharmacies participating in the program to:

*Ship only FDA-approved drugs and follow other agency rules regarding the processing and handling of drugs;
*Offer patients counseling on their medications;
*Maintain patient confidentiality;
*Document where drugs are manufactured; and
*Litigate any case concerning reimported drugs in Rhode Island courts.

In addition, the rules would prohibit the reimportation of several controlled substances, drugs that can spoil in transit, commonly counterfeited drugs and some other types of drugs (Kaiser Daily Health Policy Report, 6/14). According to the Journal, participants at the hearing criticized the liability insurance requirement more than others in the proposed rules.

Comments

Thomas McDonough -- consultant for Canada Direct Discounters, a store that helps residents purchase prescription drugs from Canada -- said, "Some of the provisions in these regulations are going to be major roadblocks." McDonough said the insurance requirement is "certainly excessive and a deal breaker." Donald Williams, director of health services regulations for the state, said following the hearing that officials arrived at the $5-million requirement by reviewing past settlements ranging from less than $1 million to $10 million. Matthew Van Hook, a lawyer representing the Pharmaceutical Research and Manufacturers of America, said that the proposed regulations would increase safety but are inadequate because in-state pharmacies are subject to more stringent oversight. Van Hook said, "This country is much safer than virtually any othercountry and it's because of the tight regulatory system that we have." The state health department will accept written comments on the regulations for the next two weeks before deciding whether to move forward with them. If revisions are made, another hearing will be held (Providence Journal, 6/16).

http://www.kaisernetwork.org/daily_reports/rep_index.cfm?DR_ID=30828

3M system will track prescription drugs
Neal Gendler
Star Tribune - Minneapolis
June 15, 2005

Texas Instruments and 3M jointly will develop a system using radio frequency identification tags in an effort to meet federal guidelines that intend to ensure security of prescription drugs and combat drug counterfeiting. The companies said Tuesday they'll apply radio frequency identification (RFID) technology currently used by retailers to track inventory so pharmacists can verify that a bottle of pills was packaged by the original manufacturer. The second phase of their development would create an "electronic pedigree," showing each time the product is handled on the way to the drugstore. The Food and Drug Administration (FDA) has set a goal of widespread commercial use of RFID technology by the end of 2007, saying it's "critical to ensuring the long-term safety and integrity of the U.S. drug supply." It says that in some countries, drug counterfeiting is so pervasive that some patients are more likely to get a counterfeit than a genuine medication.

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CDC Releases Recommendations for Flu Vaccine, Provides Assurances About Supply

The U.S. should have an adequate supply of flu vaccine for all residents who seek vaccinations this year, but physicians should first vaccinate high-risk individuals, such as Hurricane Katrina evacuees who have moved into shelters, federal health officials said on Wednesday, USA Today reports (Szabo, USA Today, 9/15). CDC expects four suppliers to provide as many as 97 million doses of flu vaccine this year "to avoid the shortages that took place last year," the Los Angeles Times reports. CDC expects 60 million doses of flu vaccine from Sanofi Pasteur and eight million doses from GlaxoSmithKline, as well as three million doses of nasal-spray vaccine from MedImmune. In addition, CDC expects as many as 26 million doses of flu vaccine from Chiron, whose manufacturing facility in Britain was closed last year because of contamination concerns (Piller, Los Angeles Times, 9/15). The Chiron facility must pass a final FDA inspection before the company can distribute flu vaccine (Condon, Hartford Courant, 9/15). Flu vaccines this year protect against three major strains: the New Caledonia and Shanghai strains, which were in the vaccine last year, and the new California strain (Los Angeles Times, 9/15).

Guidelines

In the event that Chiron provides no doses of flu vaccine this year, the U.S. would have an adequate supply of the vaccine for 71 million residents (CQ HealthBeat, 9/14). Chiron spokesperson Alison Marquiss also said that the company could not begin to distribute flu vaccine until the end of September or early October (USA Today, 9/15). As a result of the continued uncertainty, CDC has asked physicians to delay flu vaccinations for lower-risk patients until Oct. 24. At a briefing in Washington, D.C., sponsored by the National Foundation for Infectious Diseases, CDC Director Julie Gerberding said that physicians should first provide flu vaccinations to adults older than age 65, children ages six months to 23 months, and individuals who live with or care for infants younger than age six months. Others who should receive flu vaccinations first include individuals with chronic conditions, nursing home residents and pregnant women (CQ HealthBeat, 9/14). Gerberding also said that elderly hurricane evacuees, as well as evacuees of all ages who have moved into shelters, should receive flu vaccinations first (AP/Las Vegas Sun, 9/14). According to the Times, outbreaks of flu are more likely in shelters because of crowding (Los Angeles Times, 9/15). Sanofi Pasteur plans to provide 200,000 of the first available flu vaccinations to hurricane evacuees who have moved into shelters (AP/Las Vegas Sun, 9/14). CDC has not made similar distribution recommendations for the MedImmune nasal-spray flu vaccine FluMist -- which is recommended only for healthy individuals ages five to 49, except for pregnant women (USA Today, 9/15). Jeanne Santoli, deputy director of immunization services at CDC, also recommended FluMist for health care workers (CQ HealthBeat, 9/14).

http://www.kaisernetwork.org/daily_reports/rep_index.cfm?DR_ID=32588

Getting Your Health Care at Wal-Mart
To Boost Sales, Retail Chains: Open In-Store Clinics; A Strep Test and a Bar of Soap
Jane Spencer
The Wall Street Journal
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Americans can increasingly get basic medical care in the same place they buy toothpaste and light bulbs.

In a development that has broad implications for the nation's primary-care system, a rising number of major pharmacy and retail chains -- including CVS Corp., Wal-Mart Stores Inc. and Target Corp. -- are opening in-store health clinics. They offer patients fast access to routine medical services such as strep-throat tests, sports physicals and flu shots. The clinics, which typically charge between $25 and $60 per visit, don't require an appointment and are open during pharmacy hours including evenings and weekends. To keep costs down, they are staffed by nurse practitioners, who can legally treat patients and write prescriptions in most states.

The trend is rapidly spreading in pharmacy chains as they look for ways to stem losses to mail-order pharmacies and big-box stores. Three of the nation's largest drugstore chains -- Rite Aid Corp., Brooks Eckerd Pharmacy and Osco Drug -- have announced plans to open health clinics in the coming months. All three have partnered with a Pennsylvania-based health-care start-up called Take Care Health Systems LLC that will lease space inside the pharmacies and operate the clinics.

Take Care is also in talks with Walgreen Co., the nation's largest pharmacy chain (by sales volume). The first Take Care clinics will open at Rite Aid stores in Portland, Ore., later this month; Take Care aims to have 1,300 clinics open by the end of 2007.

Other major chains have been testing the in-store clinics. CVS and Target are working with Minneapolis-based MinuteClinic to open clinics at stores in markets including Minneapolis, Baltimore and Nashville. Wal-Mart is working with InterFit Health and other companies to open clinics in Oklahoma, Arkansas, Florida and other states. (The pharmacy chains must partner with outside companies because federal health-care laws banning "self referrals" prohibit pharmacy chains from running their own clinics.)

The new clinics are aimed at everyone from harried parents dropping by with sick kids on the weekend, to busy professionals ducking in for a prescription during work hours. While the retailers don't profit directly from the new services, the hope is that the clinics will boost business if patients fill their prescription at the store pharmacy, or pick up other items on their way out. (Target's MinuteClinics even offer patients a clip-on beeper after they sign in, to encourage patients to shop until the nurse practitioner is ready to see them.)

The trend is drawing criticism from some doctors groups, who could lose business if patients turn to the clinics for basic care. Doctors also contend that patients could wind up with lower-quality care because the clinics don't have physicians on-site.

"Serious illnesses sometimes present with simple symptoms," says Edward Hill, president of the American Medical Association. "A cough might be something as simple as a cold, or something as serious as congestive heart failure. The ability to ferret out the 20% of serious illnesses that present with simple symptoms is what we went to medical school for."

But some patients are more concerned about convenience. When Terri Whitesel, 56 years old, who runs a marketing consultancy in Minneapolis, had an allergic reaction to a bug bite last month, she dashed into a MinuteClinic at a Target in between meetings at work. "I didn't want to go to the doctor and sit around waiting with a bunch of people who are really sick," says Ms. Whitesel.

The nurse practitioner was busy with another patient, but Ms. Whitesel wrote down her name, got a beeper at the check-in counter, and shopped for birthday cards until the nurse beeped her five minutes later. The entire visit took less than 15 minutes and she wound up with a prescription for an anti-inflammatory drug.

Both MinuteClinic and Take Care work with a network of local physicians who are available by phone if the nurse practitioner needs help with a diagnosis. And the companies say the clinics can act as an entryway to the primary-care system because they offer referrals to patients who don't have a doctor.

The companies limit their services to a strict list of roughly 30 basic services and diagnoses, ranging from athlete's foot to tetanus shots. Neither company allows nurse practitioners to prescribe drugs for health situations that require continuing care such as antidepressants, birth control or heart medications.

Health insurers have embraced the concept because the clinics promise considerable savings. While a typical doctor visit for a basic illness costs an insurer about $110, a visit to one of the clinics usually costs under $60. In addition, the clinic services are far cheaper than the emergency room, which is where patients often wind up when they need medical care outside business hours. (A strep throat test at the emergency room can cost over $300.)

Some insurers are actively encouraging patients to use the clinics by lowering the co-pay. In Minnesota, companies including Blue Cross Blue Shield of Minnesota and Graco Inc., have reduced or eliminated co-pays for employees who opt to use a MinuteClinic instead of a doctor. Take Care has deals in place with several insurers in Portland.

Chain drugstores have been grappling with relatively flat sales for the past few years. While pharmacies have broadened their offerings over the past couple of decades, and now offer everything from photo developing to outdoor grills, prescription-drug sales still account for about 68% of their business. To hold onto that business, pharmacies are increasingly trying to establish themselves as wellness centers that offer a constellation of health-care services related to prescriptions.

The management teams behind both of the leading companies in the field -- Take Care and MinuteClinic -- have experience in other consumer-focused industries. MinuteClinic's new chief executive officer, Michael C. Howe, is the former president and CEO of the Arby's fast-food chain, and previously worked for KFC. Hal Rosenbluth, chairman of the board of Take Care, is the former CEO of Rosenbluth International, a travel company acquired by American Express Co. in 2003 in a deal valued at over $300 million.

Take Care's business model has been influenced by Mr. Rosenbluth's background in the travel industry, and the clinic model relies heavily on technology to increase the efficiency of care. When patients arrive, they check themselves in at a touch-screen computer terminal -- much like an airline self-check-in kiosk -- where they can swipe a credit card and enter basic information about their symptoms and family history.

In one of the more-novel uses of technology employed by Take Care, a computer software program will be involved in actually diagnosing illnesses. The patient's sign-in information will be transmitted electronically to a computer terminal inside the treatment room, where the nurse can enter additional information about the patient's symptoms and conditions as he or she talks with the patient.

The software system will eventually generate a diagnosis and a recommended course of treatment. If the nurse practitioner disagrees with a computer-generated diagnosis, he or she can opt to override the system. When a prescription is written, it will be transmitted electronically to

the store pharmacy, or another pharmacy. The system will also create an electronic medical record for each patient that can be transferred to a primary-care physician.